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(54) **HEART VALVE DELIVERY SYSTEM AND METHOD WITH ROTATIONAL ALIGNMENT**

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(57) **ABSTRACT**

(21) Appl. No.: **16/944,818**

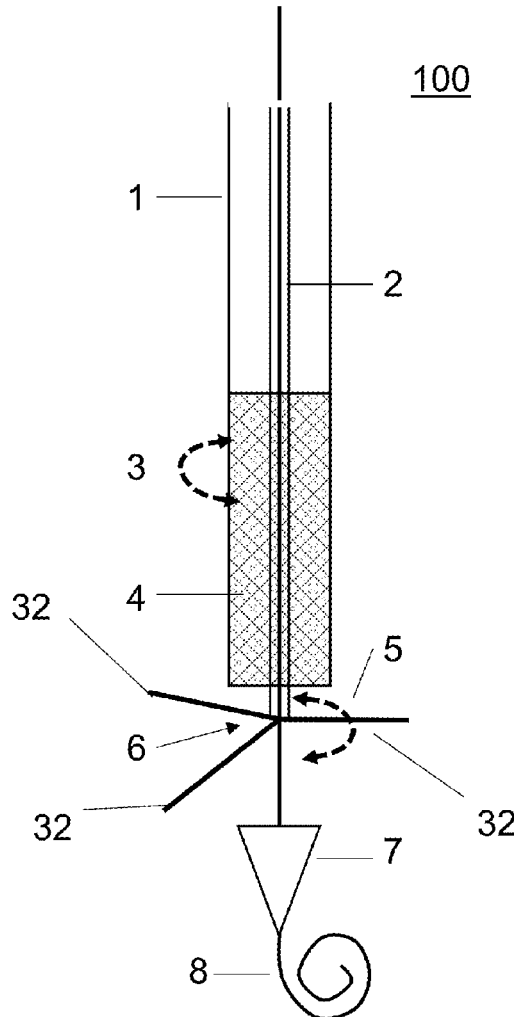
A delivery system for a transcatheter heart valve (THV) to a subject is provided, the delivery system includes a delivery catheter housing the THV therein; an elongated member for receiving the THV thereon and having an accessory extending from the distal portion thereof, the accessory comprising a plurality of components for alignment with commissures of the THV during delivery of the THV, and a rotational member connected to the elongated member to rotate the accessory and THV together to align with a native or bioprosthetic valve commissure or valve leaflet at a desired angle.

(22) Filed: **Jul. 31, 2020**

Related U.S. Application Data

(63) Continuation of application No. PCT/US19/50231, filed on Sep. 9, 2019.

(60) Provisional application No. 62/728,346, filed on Sep. 7, 2018.



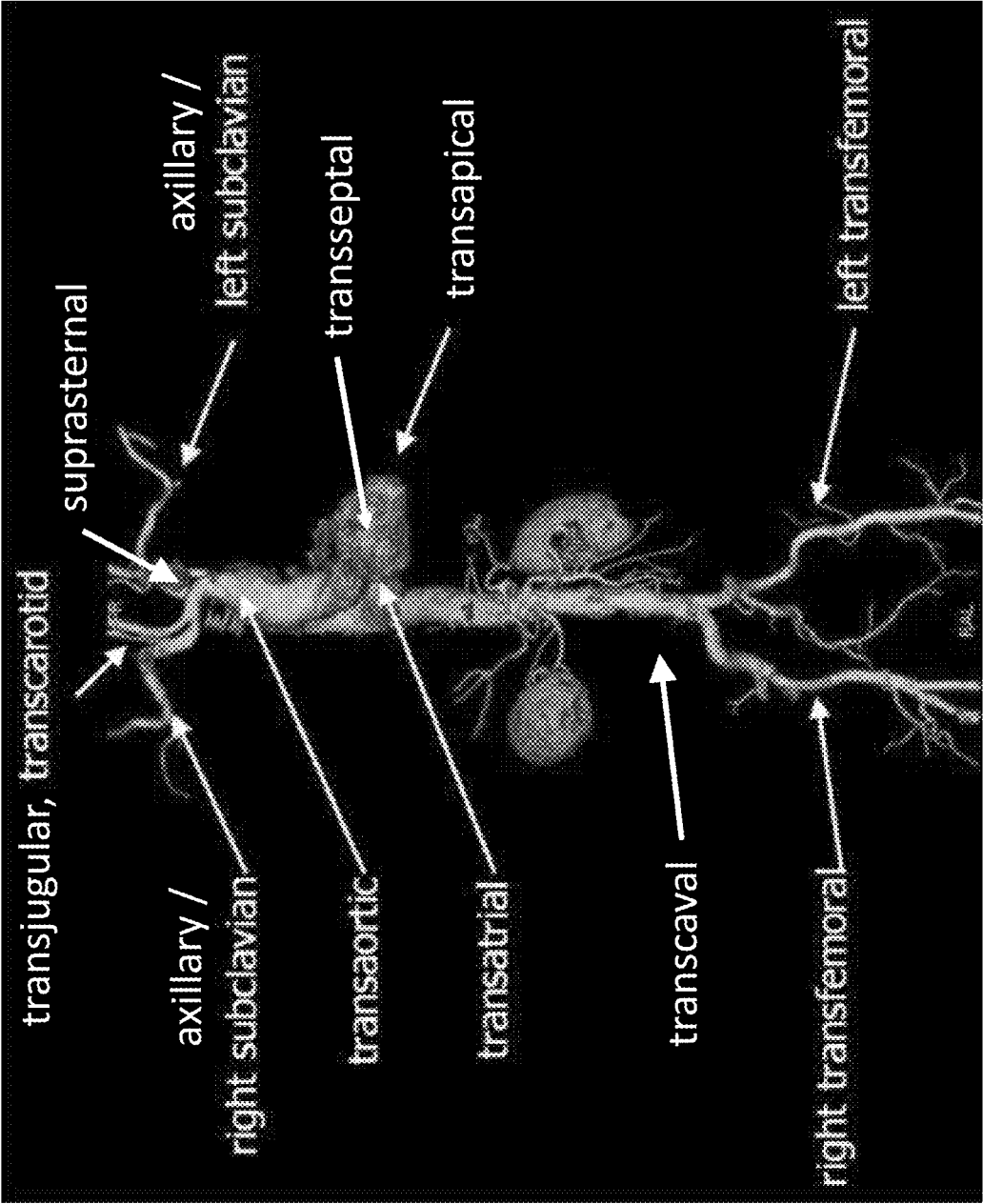


FIG. 1

FIG. 2B

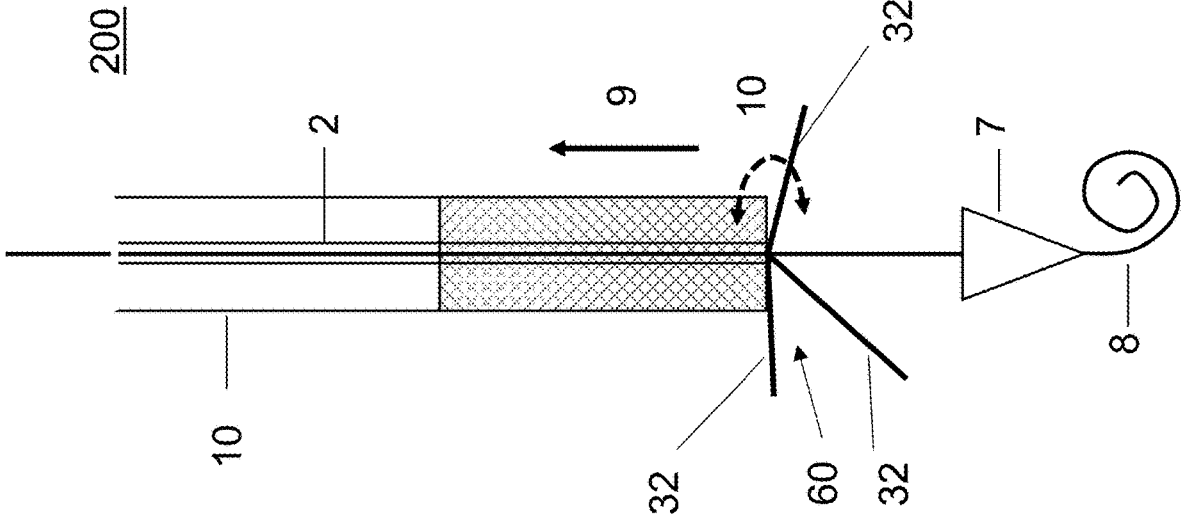


FIG. 2A

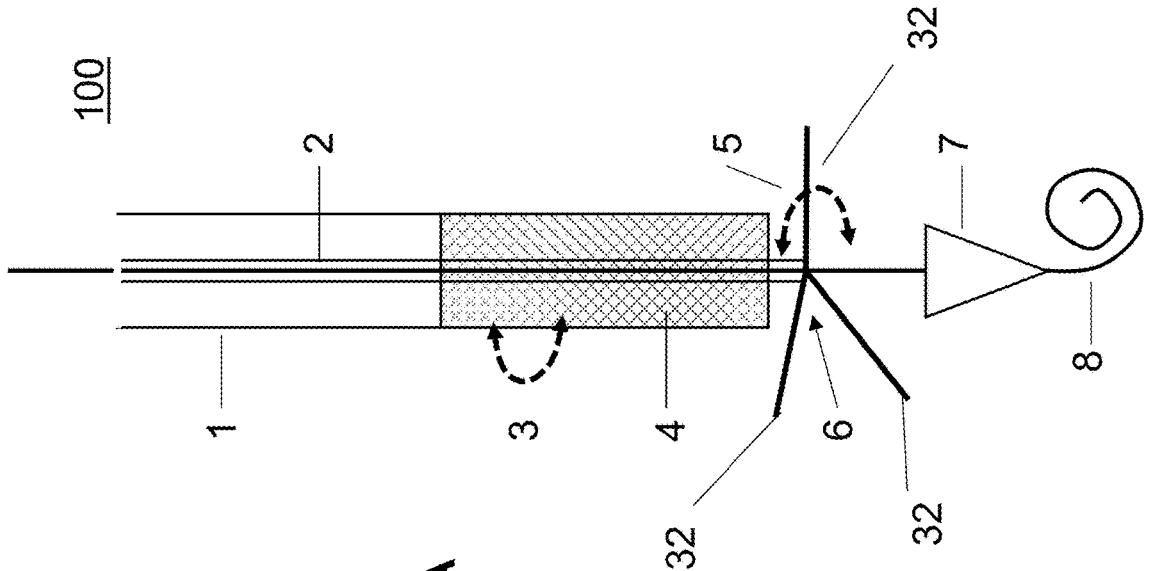


FIG. 3A

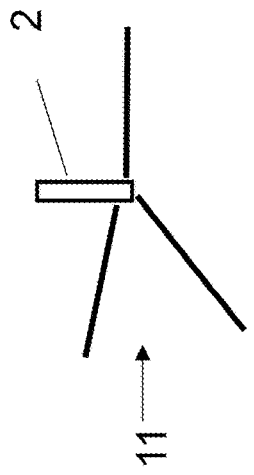


FIG. 3B

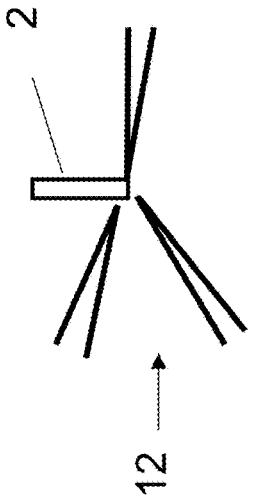


FIG. 3C

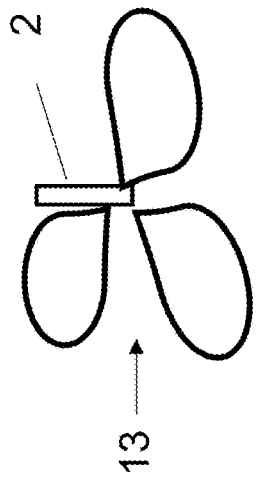


FIG. 3D

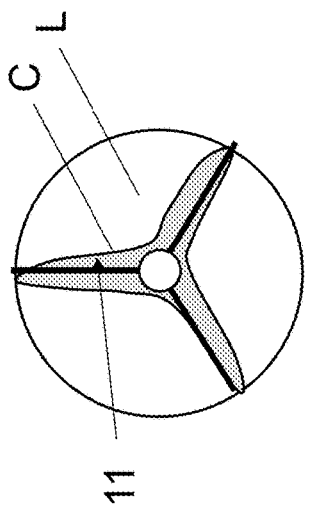


FIG. 3E

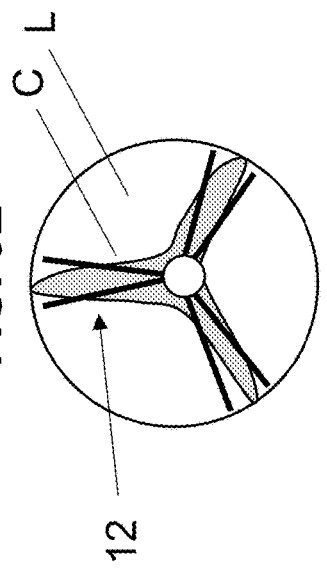
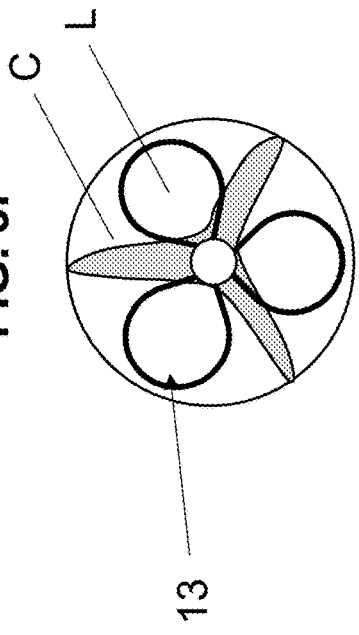


FIG. 3F



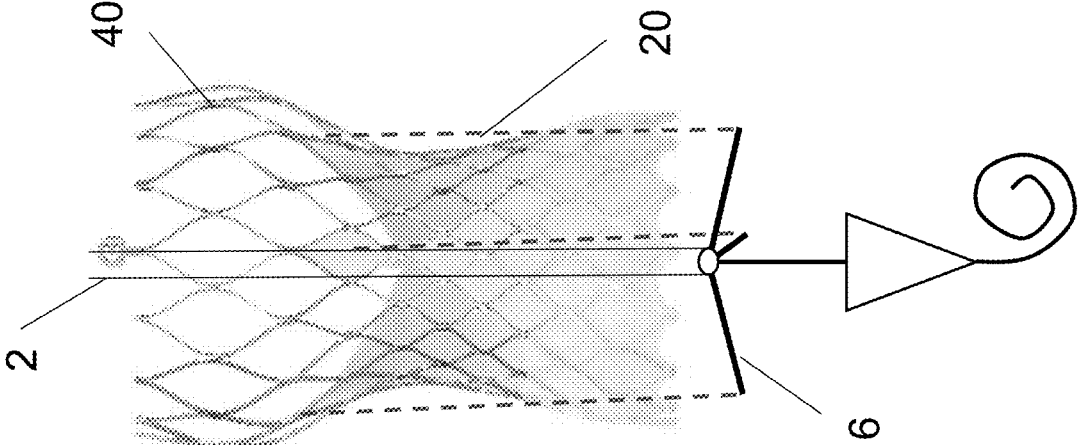


FIG. 4B

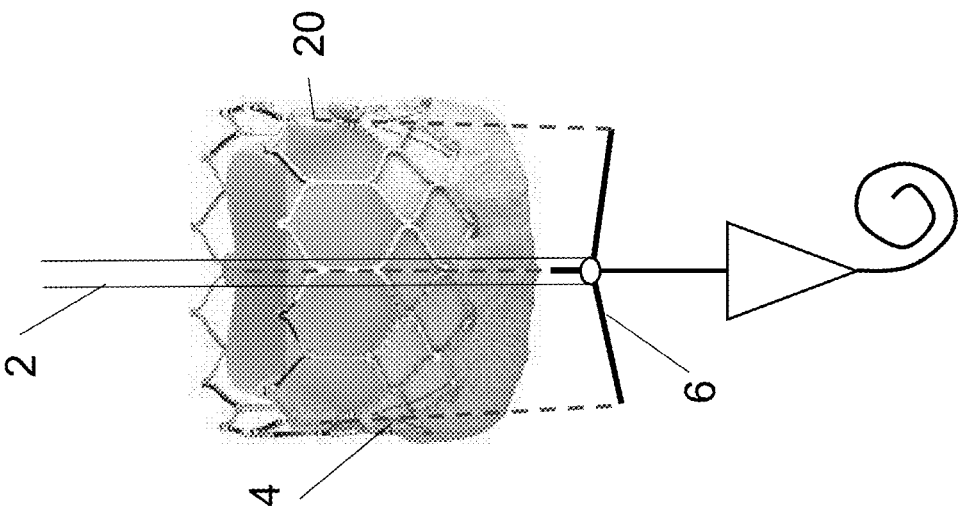


FIG. 4A

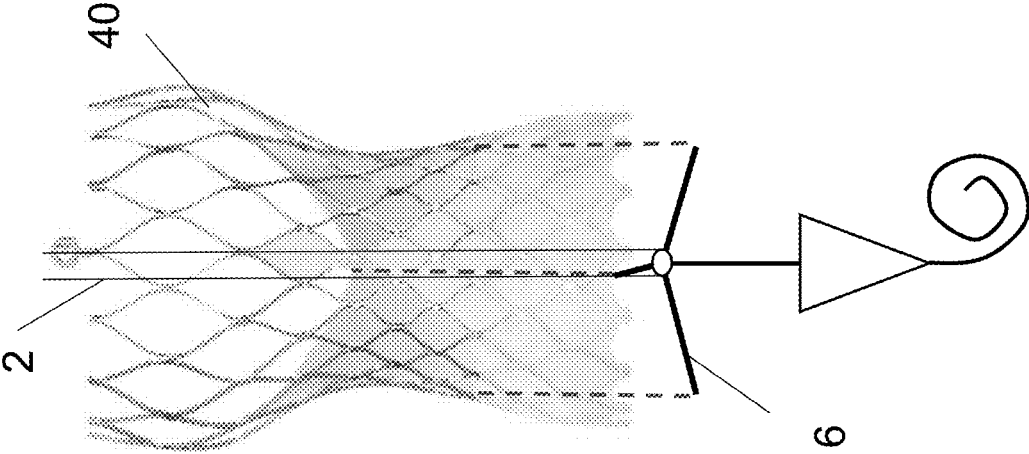


FIG. 4C

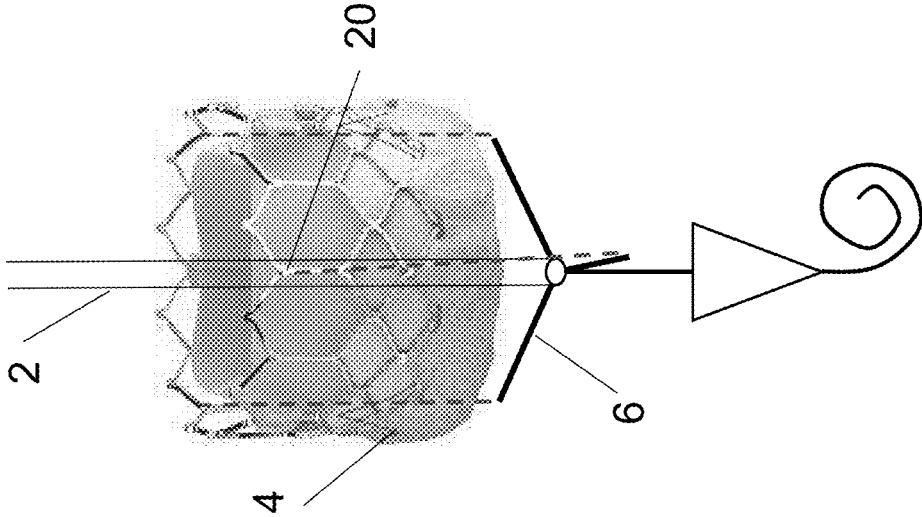
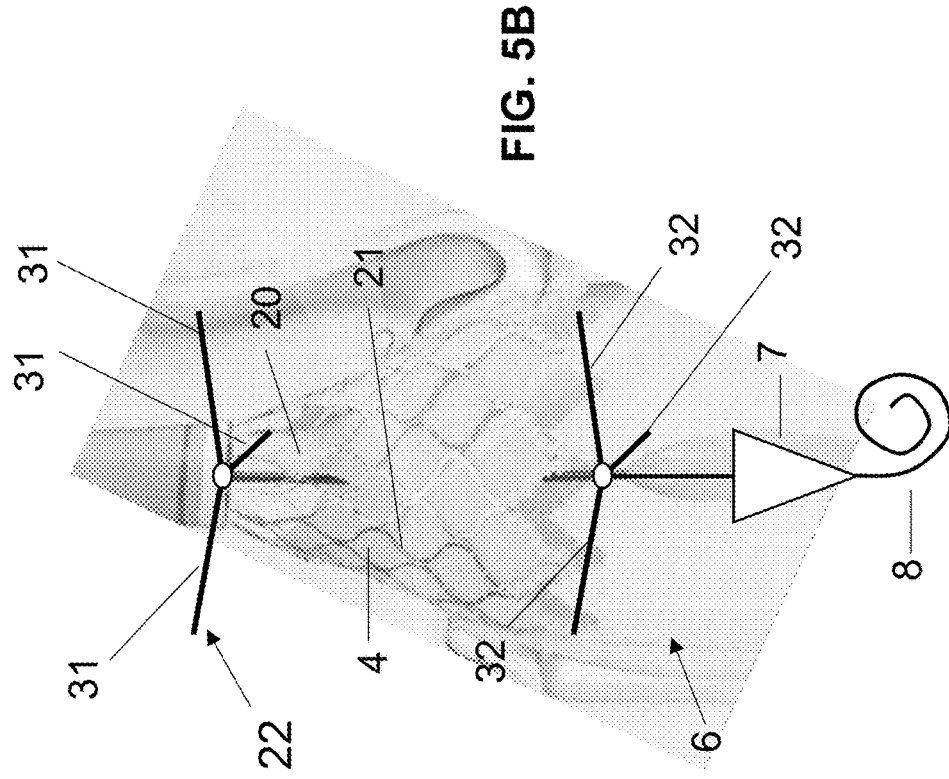
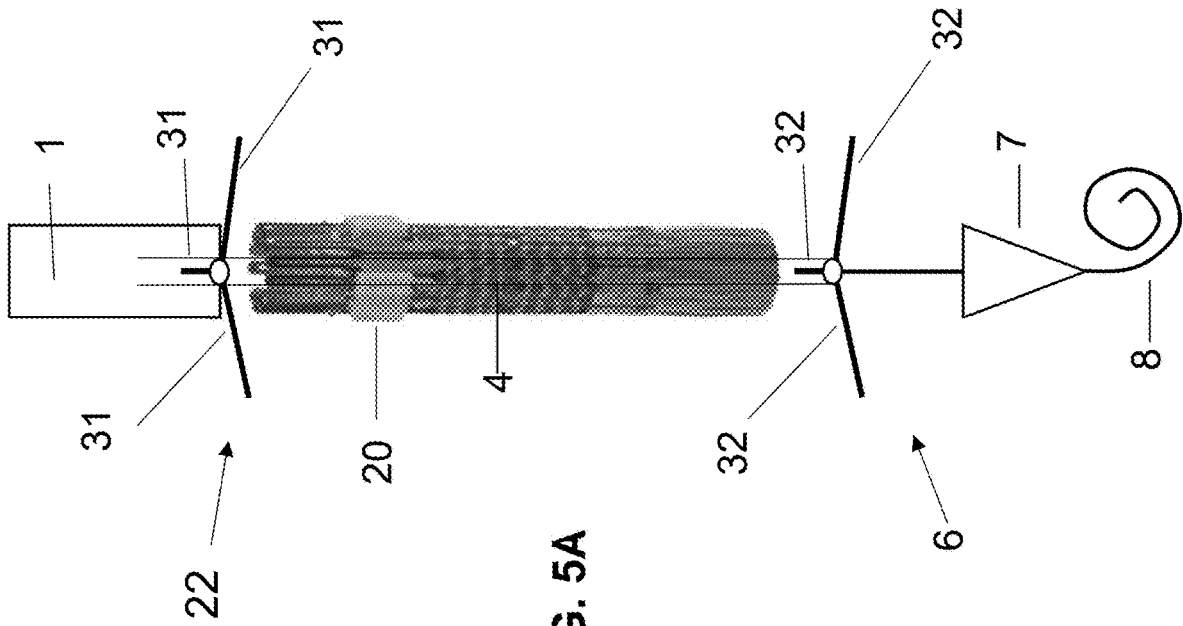


FIG. 4D



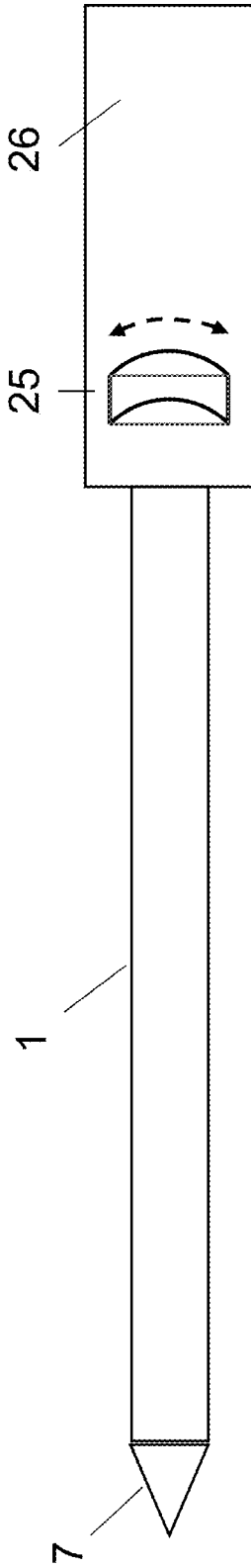


FIG. 6A

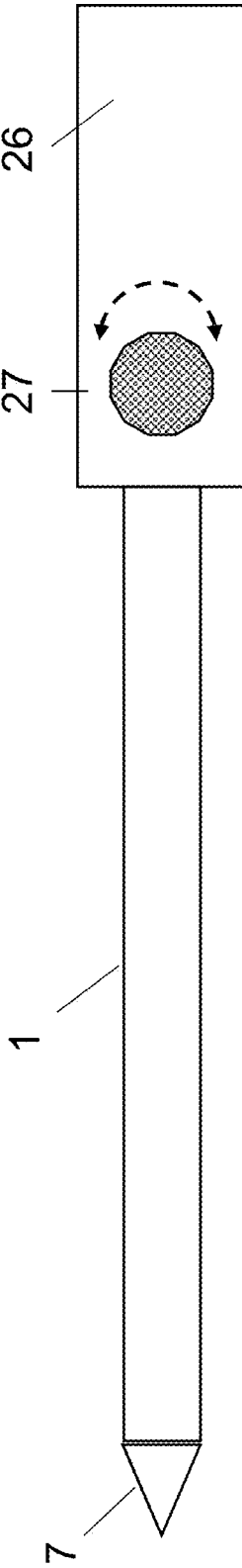


FIG. 6B

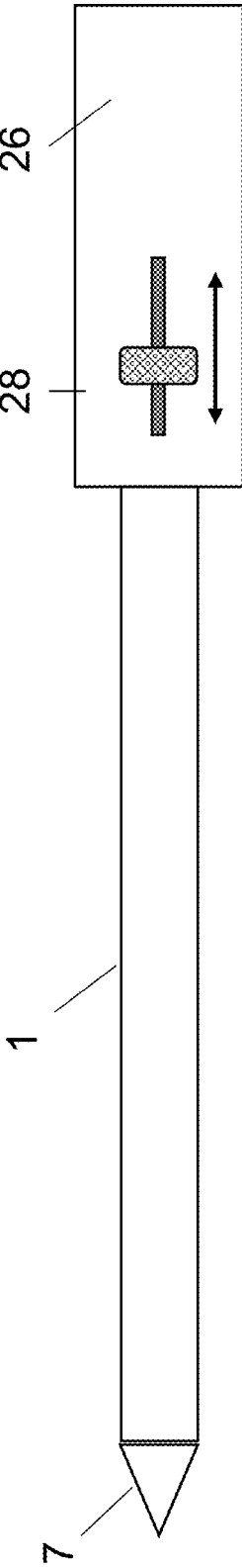


FIG. 6C

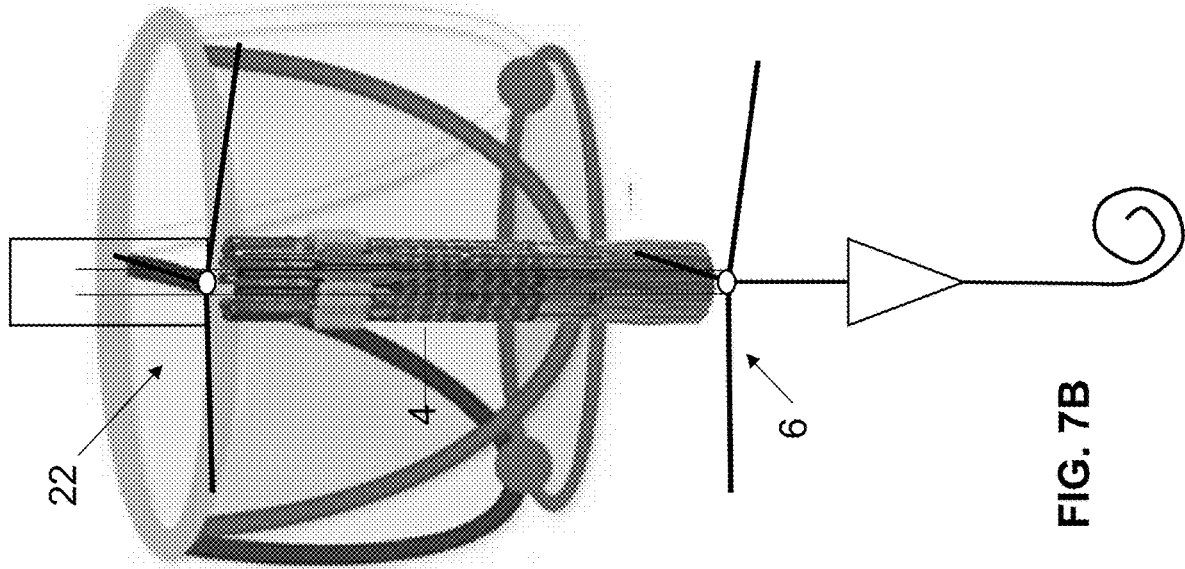


FIG. 7B

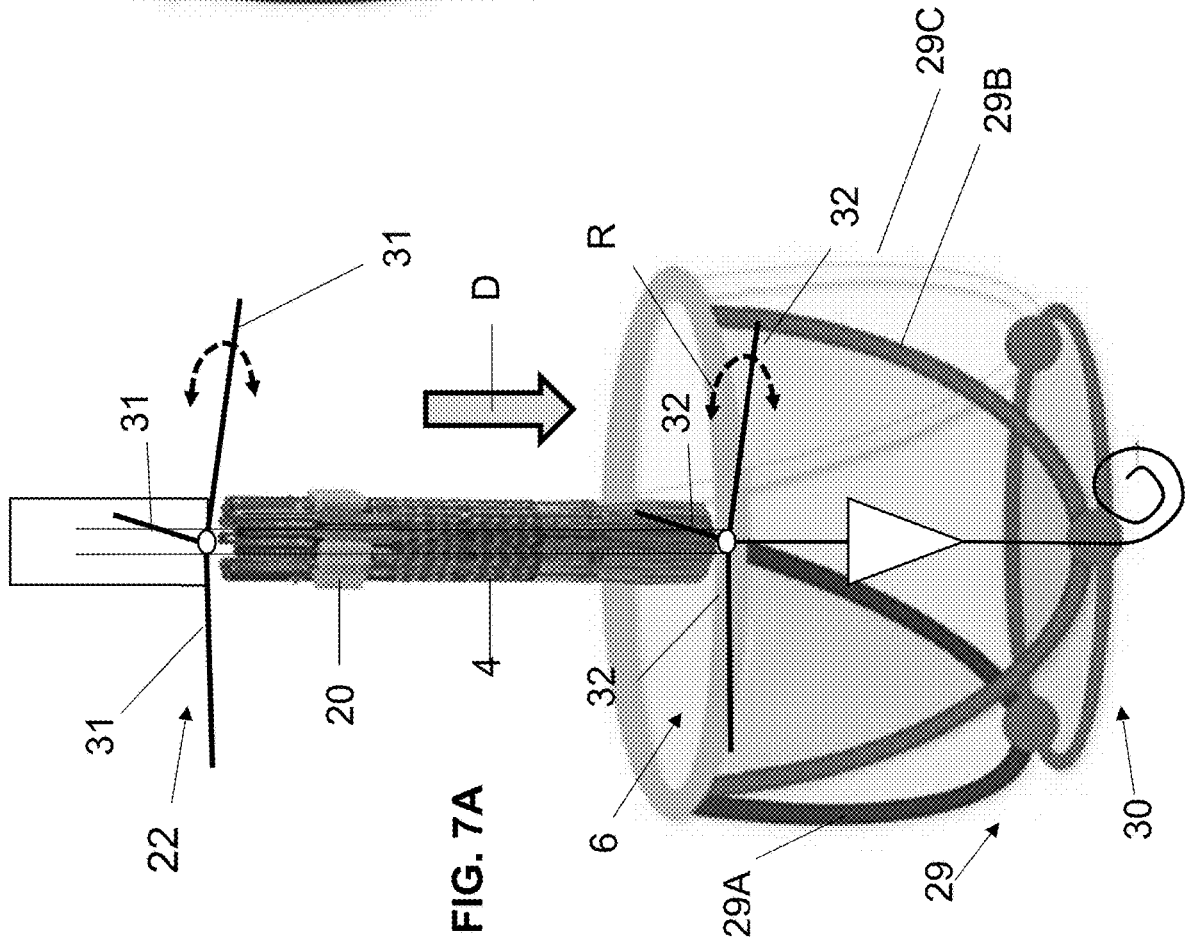


FIG. 7A

FIG. 8B

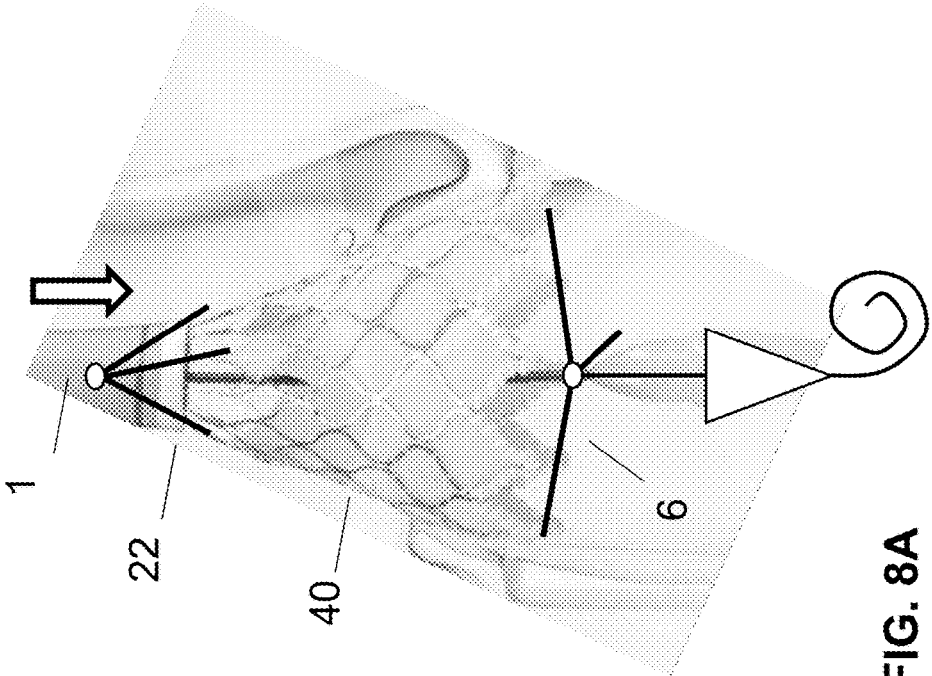
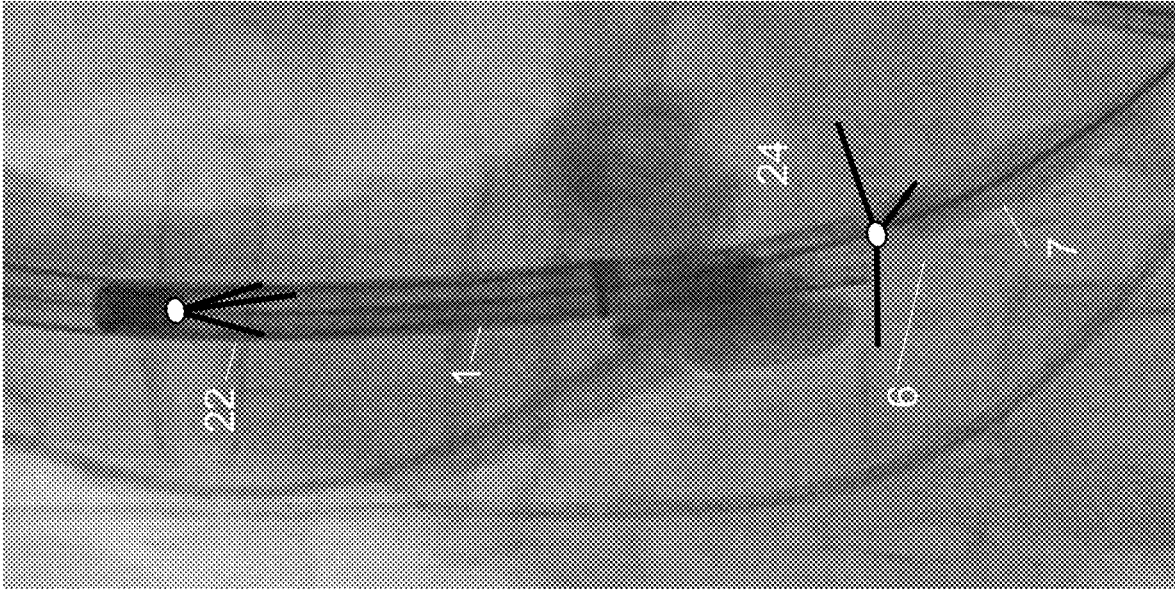


FIG. 8A

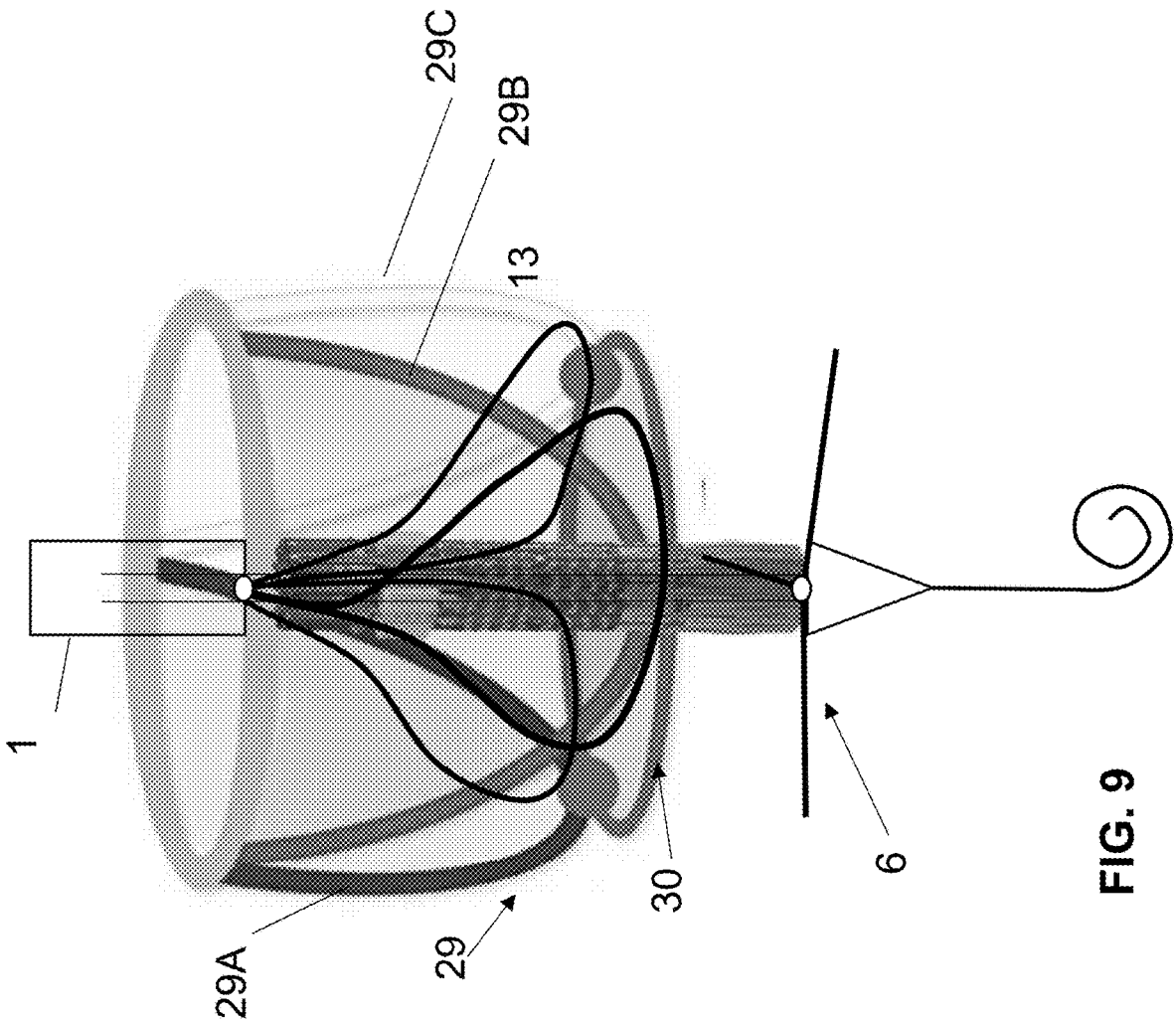


FIG. 9

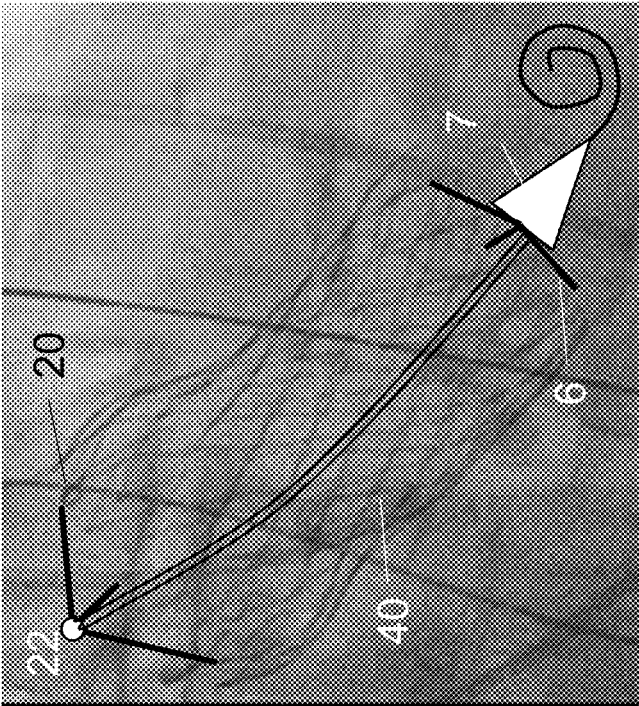


FIG. 10B

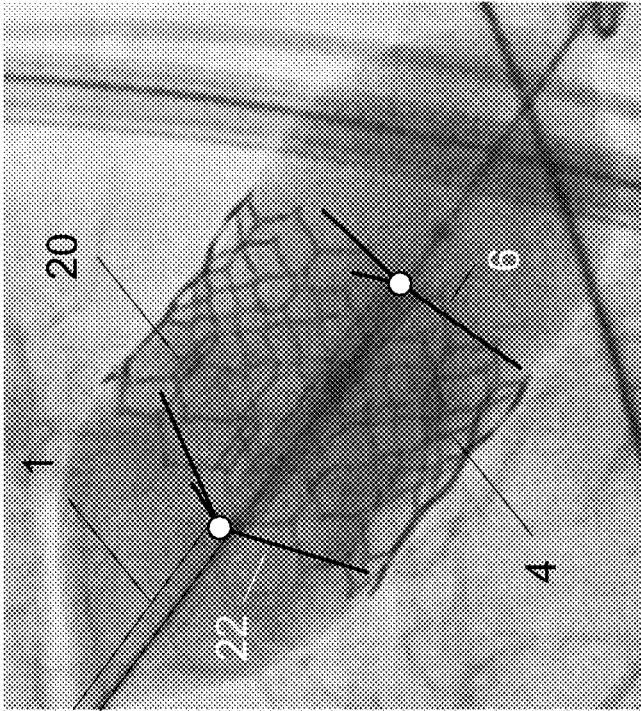


FIG. 10A

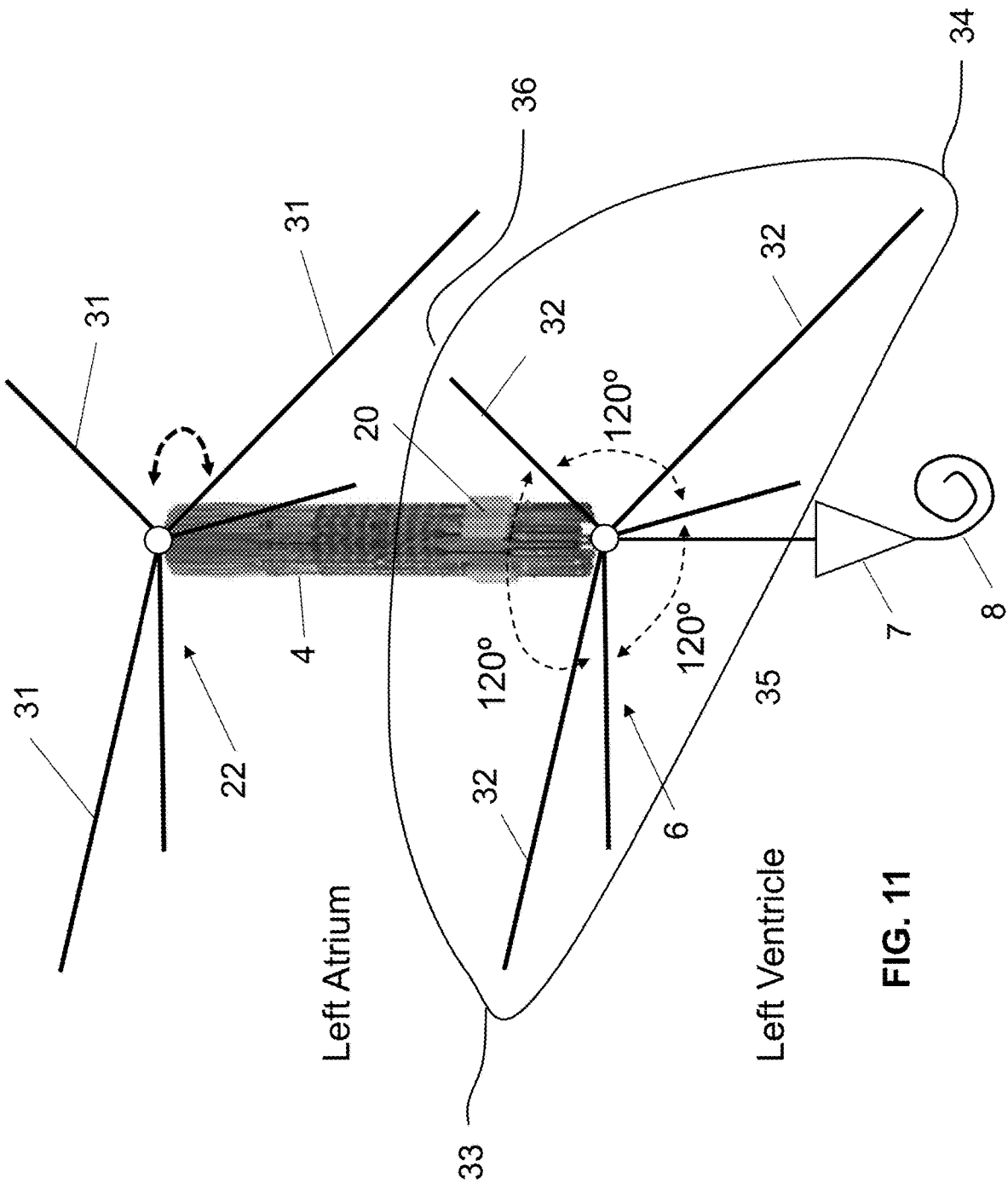


FIG. 11

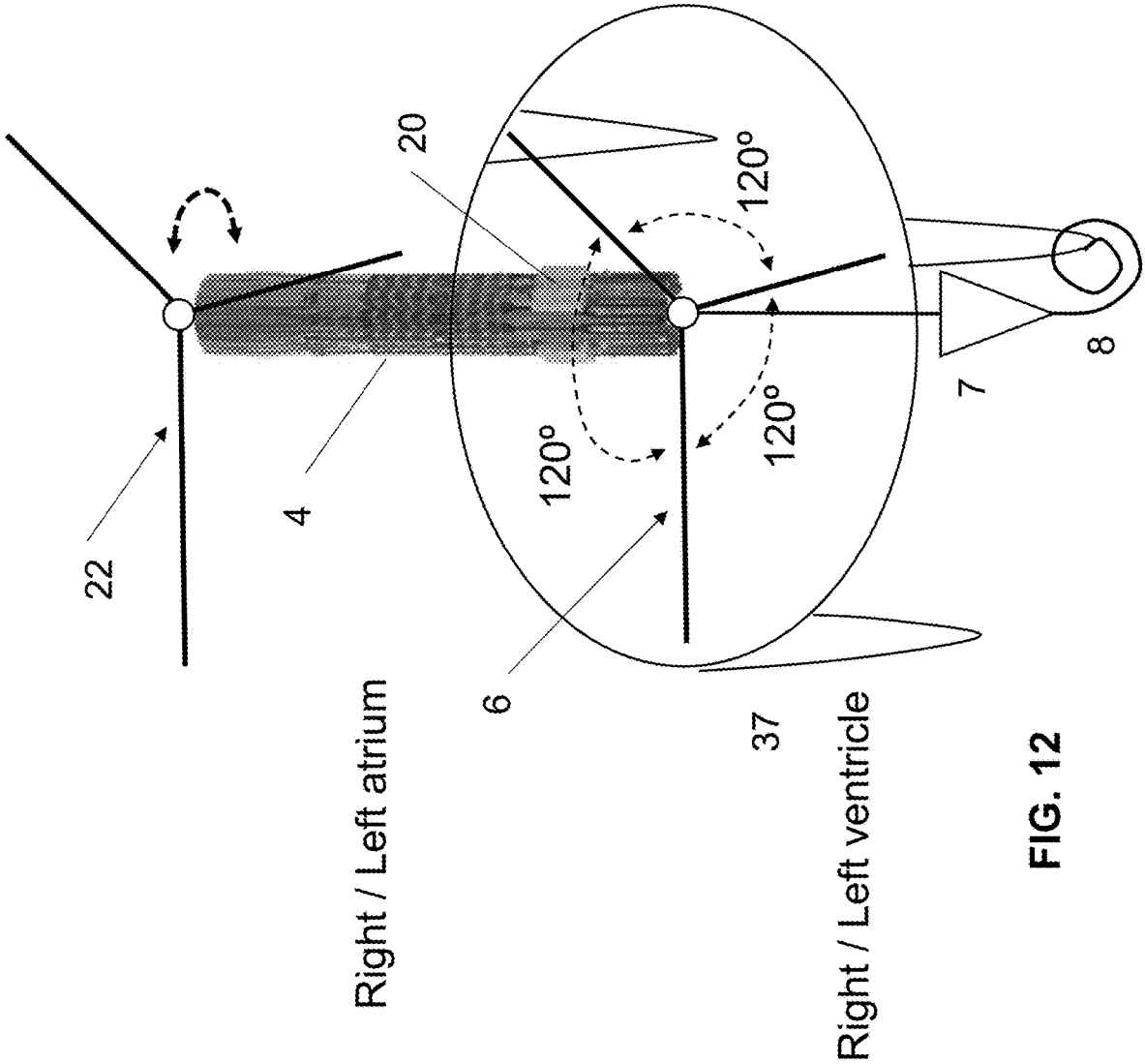


FIG. 12

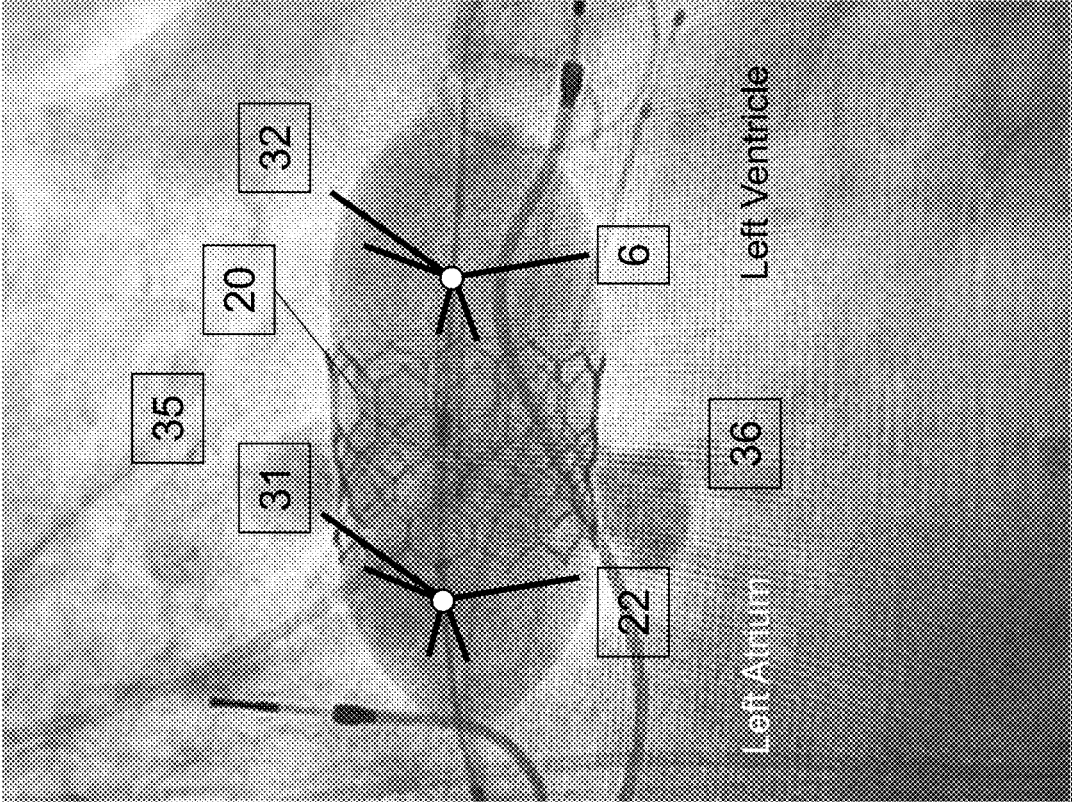


FIG. 13A

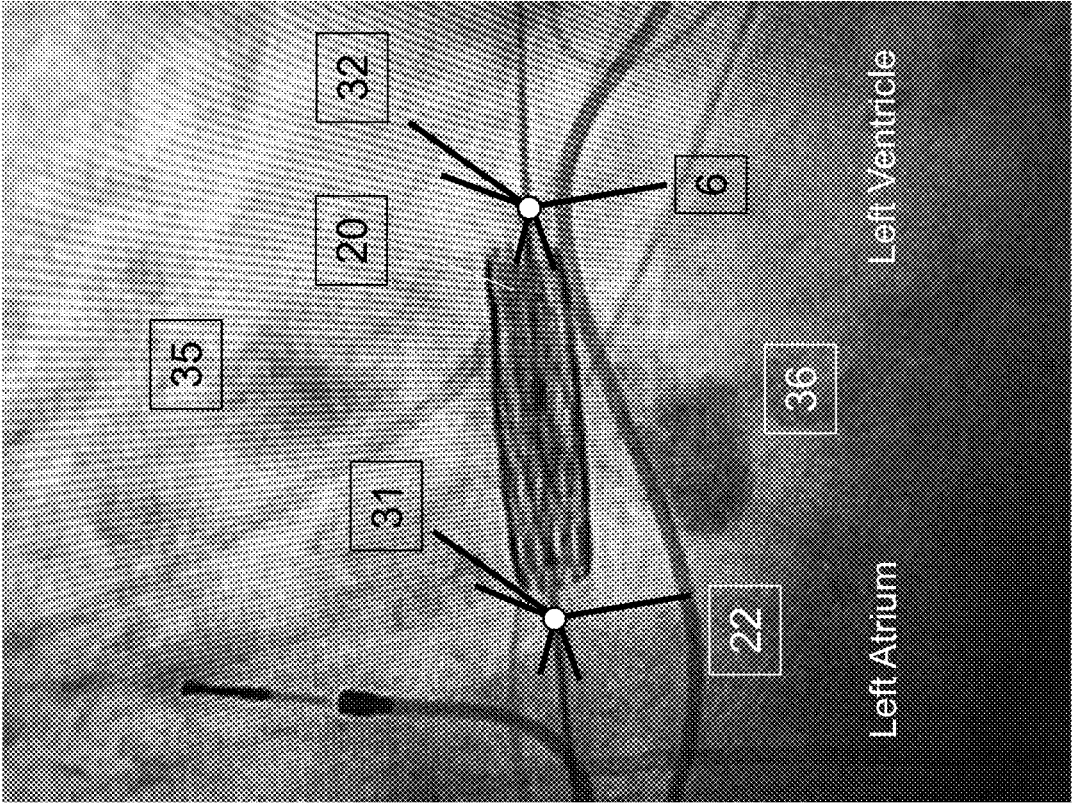


FIG. 13B

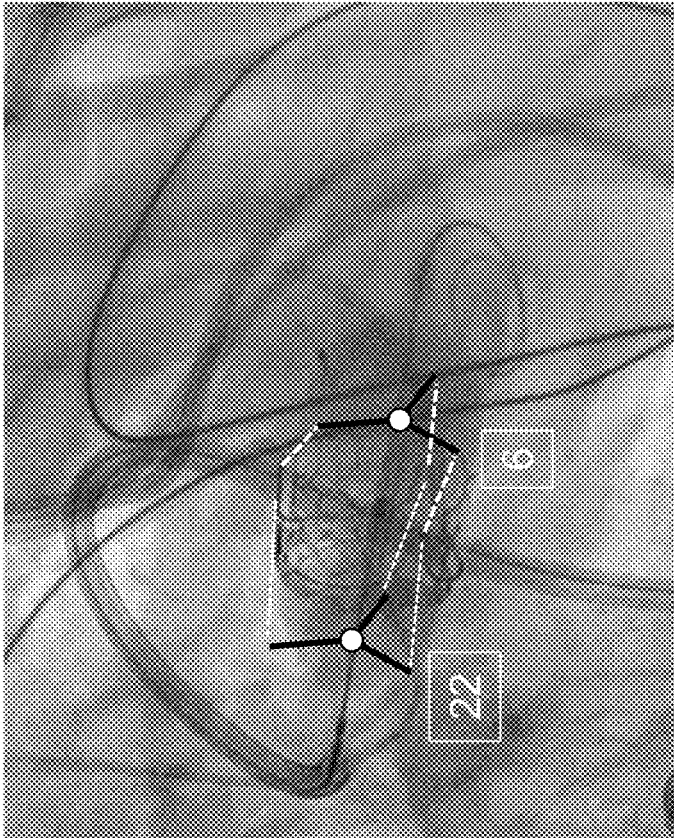


FIG. 14A

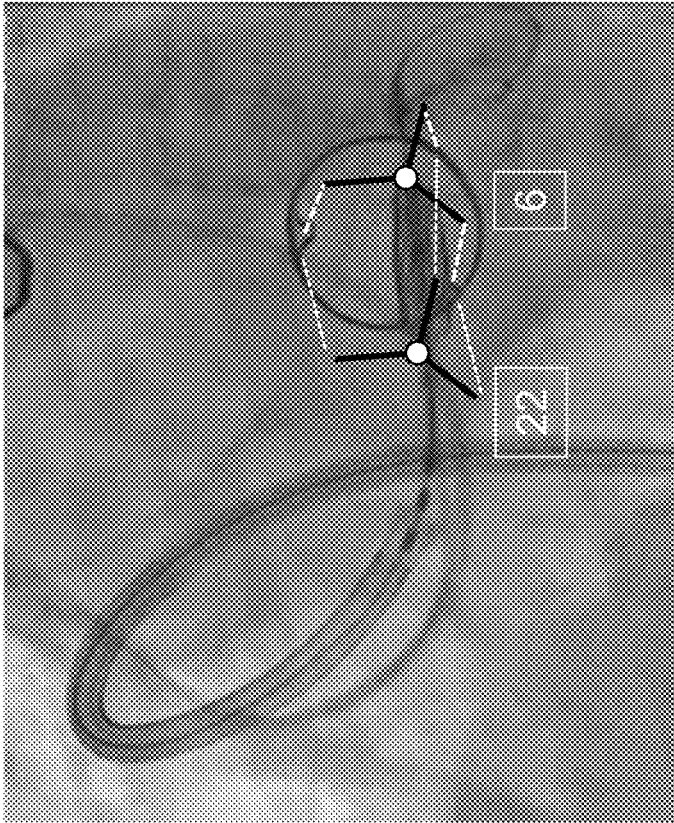


FIG. 14B

HEART VALVE DELIVERY SYSTEM AND METHOD WITH ROTATIONAL ALIGNMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a Continuation of International Application No. PCT/US19/50231, filed Sep. 9, 2019 which claims priority to U.S. Provisional Application 62/728,346, filed Sep. 7, 2018, the entirety of which are incorporated herein by reference.

FIELD

[0002] A method and apparatus configured for delivery and implantation of a prosthetic heart valve in a native or prosthetic heart valve.

BACKGROUND

[0003] Transcatheter heart valve (THV) replacement in failing native and bioprosthetic valves are becoming increasingly common. THV replacement of native and bioprosthetic aortic, mitral, tricuspid and pulmonic valves has been successfully performed. Transcatheter aortic valve replacement (TAVR) is becoming the preferred treatment in patients with symptomatic severe aortic stenosis and results on comparing surgical vs transcatheter AVR in low risk patients will be available in 2019. Predicted market growth for TAVR to treat severe aortic stenosis is significant. In younger, low risk patients, the long-term durability of TAVR remains unknown, and a significant number of these patients have or will develop significant coronary artery disease, requiring diagnostic and therapeutic interventions. One of the major difference between surgical aortic valve replacement and TAVR is, in surgery the valves are always aligned to native commissures and hence mimic the physiological opening and closing and may influence durability and function. Early evidence has pointed to the fact that, commissural alignment may also influence function of the THV after TAVR. Further, coronary access after TAVR is known to be more difficult than after surgical aortic valve replacement. This is due to the presence of native aortic valve leaflets, the THV frame occupying the aortic root and in some patients due to presence of commissure in front of the coronary ostia. Published case series have shown that coronary angiography and PCI after TAVR are more challenging, requiring more radiation exposure and IV contrast. In urgent or emergency situation such as acute myocardial infarction, the issue of timely coronary access after TAVR is critical to life and death. By aligning the THV commissures to the native commissures, there is a likelihood that there will be better function but more importantly easier access to the coronary ostia. Currently, there is no predictable and consistent method of aligning the THV neo-commissures with the native or bioprosthetic aortic valve commissures with help of a delivery system.

[0004] Methods have been developed to split the native or bioprosthetic aortic valve leaflet to facilitate coronary reaccess or avoid coronary obstruction during TAVR. However, if a THV commissure is placed facing the coronary ostium, such a method would not be feasible. This speaks to the importance of developing a device that can align the THV commissures to native commissures.

[0005] A delivery system that can consistently deliver a THV to the native or bioprosthetic aortic valve with the

neo-commissures aligned with the native or bioprosthetic aortic valve commissures is needed, since it would reduce the risk of neo-commissural tab interference with coronary orifices, making coronary reaccess after TAVR less difficult.

[0006] The ability for a delivery system to deliver and help align a THV to native or bioprosthetic valve extends beyond the aortic valve. The ability to deliver and deploy a THV in a native mitral valve with calcification, bioprosthetic pulmonic, mitral and tricuspid valve with specific angle of alignment between neo-commissures and bioprosthetic valve commissures may help improve THV frame expansion and anchor against the bioprosthesis. There may also be hemodynamic reasons of aligning neo-commissures with native and bioprosthetic valve commissures in a specific angle.

SUMMARY

[0007] A delivery system for a transcatheter heart valve (THV) to a subject is provided, the delivery system includes a delivery catheter housing the THV therein; an elongated member for receiving the THV thereon and having an accessory extending from the distal portion thereof, the accessory comprising a plurality of components for alignment with commissures of the THV during delivery of the THV, and a rotational member connected to the elongated member to rotate the accessory and THV together to align with a native or bioprosthetic valve commissure or a valve leaflet at a desired angle. In some embodiments, the THV is adapted for placement at the aortic valve, the mitral valve or the tricuspid valve.

[0008] In some embodiments, the components of the accessory include a plurality of radially outwardly extending projections. The components are useful to identify the THV neo-commissures or sinuses.

[0009] In some embodiments, the projections are disposed at a distal portion of the THV during delivery of the THV. In some embodiments, the projections are disposed at a distal portion of the THV during delivery of the THV.

[0010] In some embodiments, the components are atraumatic filamentous projections. In some embodiments, the components are loop-shaped projections. The components can include radiopaque components, e.g., to aid in identifying the orientation of the visible components and the THV under fluoroscopy. They may also contain materials to be distinctively visible on echocardiography to aid in THV rotational alignment and deployment.

[0011] In some embodiments, the rotational member includes a rotational wheel positioned on a proximal handle portion. In some embodiments, the rotational member includes a thumb slide positioned on a proximal handle portion. The delivery system can further include a nose cone.

[0012] The accessory can be manipulated as a part of the delivery system or independent from the rest of the delivery system. The components of the accessory have the option of being projected outward at the distal end of the delivery system and retracted within. The accessory can undergo rotation in synchrony with the THV to maintain alignment of the THV commissures/sinuses with the accessory. The accessory with its visible components can also undergo translational movement in synchrony or independently from the THV mounted on the delivery system.

[0013] Orientation of the accessory components relative to the THV after deployment is maintained to confirm the final

THV neo-commissural orientation relative to the native or bioprosthesis valve commissures.

BRIEF DESCRIPTION OF THE DRAWINGS AND FIGURES

[0014] FIG. 1 is a schematic illustrating various transcatheter approaches to deliver a prosthetic heart valve to the heart

[0015] FIG. 2A illustrates an exemplary embodiment of a device configured for delivery and implantation of a prosthetic heart valve in a native or prosthetic heart valve.

[0016] FIG. 2B illustrates another exemplary embodiment of a device configured for delivery and implantation of a prosthetic heart valve in a native or prosthetic heart valve.

[0017] FIG. 3A illustrates an exemplary embodiment of an accessory for use with the devices of FIGS. 2A and 2B.

[0018] FIG. 3B illustrates another exemplary embodiment of an accessory for use with the devices of FIGS. 2A and 2B.

[0019] FIG. 3C illustrates a further exemplary embodiment of an accessory for use with the devices of FIGS. 2A and 2B.

[0020] FIG. 3D is a view in partial section of the accessory of FIG. 3A positioned with respect to native or prosthetic valve commissures of a subject in accordance with an exemplary embodiment of the disclosed subject matter.

[0021] FIG. 3E is a view in partial section of the accessory of FIG. 3B positioned with respect to native or prosthetic valve commissures of a subject in accordance with an exemplary embodiment of the disclosed subject matter.

[0022] FIG. 3F is a view in partial section of the accessory of FIG. 3C positioned with respect to the sinuses of the native or prosthetic valve of a subject in accordance with an exemplary embodiment of the disclosed subject matter.

[0023] FIG. 4A is side view of the device of FIGS. 2A and/or 2B with portions of the accessory in substantial alignment with the commissural posts of the balloon expandable THV in accordance with an exemplary embodiment of the disclosed subject matter.

[0024] FIG. 4B is side view of the device of FIGS. 2A and/or 2B with portions of the accessory in substantial alignment with the commissural posts of the self-expanding or mechanically-expanding THV in accordance with an exemplary embodiment of the disclosed subject matter.

[0025] FIG. 4C is side view of the device of FIGS. 2A and/or 2B with portions of the accessory substantially offset from the commissural posts of the balloon expandable THV in accordance with an exemplary embodiment of the disclosed subject matter.

[0026] FIG. 4D is side view of the device of FIGS. 2A and/or 2B with portions of the accessory substantially offset from the commissural posts of the self-expanding or mechanically-expanding THV in accordance with an exemplary embodiment of the disclosed subject matter.

[0027] FIG. 5A illustrates a further embodiment of the device of FIG. 2A.

[0028] FIG. 5B illustrates the embodiment of FIG. 5A with the THV partially deployed in accordance with an exemplary embodiment of the disclosed subject matter.

[0029] FIG. 6A is an embodiment of a rotation alignment structure of the device in accordance with an exemplary embodiment of the disclosed subject matter.

[0030] FIG. 6B is another embodiment of a rotation alignment structure of the device in accordance with an exemplary embodiment of the disclosed subject matter.

[0031] FIG. 6C is a further embodiment of a rotation alignment structure of the device in accordance with an exemplary embodiment of the disclosed subject matter.

[0032] FIG. 7A illustrates the device of FIG. 6A prior to deployment of the THV positioned at the aortic root above the aortic valve annulus.

[0033] FIG. 7B illustrates the device of FIG. 6A prior to deployment of the THV, such that the component is positioned through the aortic valve annulus.

[0034] FIG. 8A illustrates re-collapse of a portion of the accessory of the device to assist in repositioning of the THV in accordance with an exemplary embodiment of the disclosed subject matter.

[0035] FIG. 8B is a fluoroscopic view of the procedure of FIG. 8A in accordance with an exemplary embodiment of the disclosed subject matter.

[0036] FIG. 9 illustrates the positioning of the device in accordance with an exemplary embodiment of the disclosed subject matter.

[0037] FIG. 10A is a fluoroscopic view illustrating the orientation of the accessory after deployment of a balloon-expandable THV.

[0038] FIG. 10B is a fluoroscopic view illustrating the orientation of the accessory after deployment of a self-expandable THV.

[0039] FIG. 11 illustrates the positioning of the device with respect to the medial commissure, the lateral commissure, the anterior annulus, and the posterior annulus of the mitral valve.

[0040] FIG. 12 illustrates the orientation of the THV and the accessory of FIG. 5A to align with the commissures of the prosthetic heart valve.

[0041] FIG. 13A is a fluoroscopic visualization of the accessory during transcatheter heart valve positioning in native mitral valve.

[0042] FIG. 13B is a fluoroscopic visualization of the accessory after transcatheter heart valve deployment in transcatheter mitral valve replacement in native mitral valve.

[0043] FIG. 14A is a fluoroscopic visualization of the accessory during transcatheter heart valve positioning in a prosthetic mitral valve.

[0044] FIG. 14B is a fluoroscopic visualization of the accessory after transcatheter heart valve deployment in transcatheter mitral valve replacement in a prosthetic mitral valve.

DETAILED DESCRIPTION OF THE DISCLOSED SUBJECT MATTER

[0045] While methods, systems and devices are described herein by way of examples and embodiments, those skilled in the art recognize that the methods, systems and devices for delivery and implantation of a prosthetic heart valve in a patient are not limited to the embodiments or drawings described. It should be understood that the drawings and description are not intended to be limited to the particular form disclosed. Rather, the intention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the appended claims. Any headings used herein are for organizational purposes only and are not meant to limit the scope of the description or the claims. As used herein, the word “may” is used in a permissive sense (i.e., meaning having the potential to) rather than the mandatory

sense (i.e., meaning must). Similarly, the words “include,” “including,” and “includes” mean including, but not limited to.

[0046] The basic components of exemplary embodiments of a device for delivery and implantation of a prosthetic heart valve in a patient are described herein. As used in the description, the terms “top,” “bottom,” “above,” “below,” “over,” “under,” “above,” “beneath,” “on top,” “underneath,” “up,” “down,” “upper,” “lower,” “front,” “rear,” “back,” “forward,” “backward” and “left,” “right” refer to the objects referenced when in the orientation illustrated in the drawings, which orientation is not necessary for using the devices or achieving the methods described herein. The term “proximal” as used herein is understood to refer to the location further away from the tip of the delivery catheter, proximal to the transcatheter heart valve. The term “distal” as used herein is understood to refer to the location closest to the tip of the delivery catheter.

Aortic

[0047] Exemplary embodiments for delivery and implantation of a prosthetic aortic heart valve in a patient are described herein. The delivery system will be either retrograde (transfemoral, axillary/subclavian, transaortic, transcarotid, transcaval, suprasternal) or antegrade (transapical) (FIG. 1). The design principles of the delivery catheter and accessory are the same but the delivery system lengths will vary based on the approach.

[0048] An exemplary embodiment of the delivery system **100** is illustrated in FIG. 2A. The system **100** includes the valve delivery catheter **1**. As indicated by arrow **3**, the delivery catheter **1** has rotational freedom. System **100** further includes accessory **6**, delivery shaft **2** for controlling accessory **6**, and nose cone **7** for passing over guide wire **8**. The accessory **6**, advanced to a position distally to the THV **4** near or at the nose cone **7**, may include three components, e.g., radially outwardly extending symmetric projections **32**.

[0049] In some embodiments, projections **32** are fabricated from Nitinol or similar material having elastic and/or shape memory characteristics. During deployment of the THV through the vascular system of the subject, the projections **32** can be compressed within the cone **7** to allow atraumatic passage of the accessory **6** to the valve location. Subsequently, the cone **7** is separately advanced distally to allow the projections **32** to extend to the radially outward configuration of FIG. 2A. In some embodiments, projections **32** can include radiopaque structures or markers to facilitate alignment of the accessory **6**, the THV **4** and the subject's anatomy.

[0050] Accessory **6** is connected to shaft **2** that is adapted to independently advance, rotate and retract accessory **6** within the delivery catheter **1**. The rotational freedom of accessory **6** with respect to delivery catheter **1** is illustrated by arrow **5**. An advantage of system **100** is that if the THV **4** needs to be recaptured and repositioned after complete deployment, and if recapturing and repositioning the device may lead to misalignment between the THV commissures and the accessory components, the accessory **6** can be manually rotated to re-align with the THV commissures to confirm orientation relative to native or bioprosthetic valve commissures.

[0051] Another exemplary embodiment of the system **200** is illustrated in FIG. 2B, and is substantially identical to system **100**, with the differences noted herein. The accessory

60 can be an integral part of the valve delivery catheter **10**, whereby proximal unsheathing of the THV will expose the accessory **60** distal to the THV and hence the three visible projections **32**. System **200** has the benefit of having a simpler delivery catheter **10** having only one movable part (composite valve delivery catheter **10** and accessory **60**) instead of two separate independently movable parts.

[0052] The components of the accessory can take a variety of shapes and lengths. For example, the accessory can include soft filamentous projections that are atraumatic to the native tissue (accessory **11** illustrated in FIG. 3A and accessory **12** illustrated in FIG. 3B). In the exemplary embodiment shown in FIG. 3A, three components, e.g., projections, are depicted. In the exemplary embodiment of FIG. 3B, accessory **12** includes three components, e.g., three pairs of projections. In some embodiments, the accessory can include “tear-drop”-shaped loops made of soft metallic composites that are flexible and atraumatic (accessory **13** illustrated in FIG. 3C). (While accessory **11**, **12** and **13** is illustrated extending from shaft **2** in FIGS. 3A, 3B, 3C, it is understood that the configurations of accessory **11**, **12** and **13** are interchangeably used in systems **100** and **200** described herein.)

[0053] In some embodiments, the projections are adjustable in length so that they can be extended/retracted as desired (not shown). In the exemplary embodiments shown in FIGS. 3A, 3B and 3C, each projection is capable of being moved independently. Furthermore, each projection can exhibit a variable radius of curvature such that the projections can be articulated (or “curled”) to conform to a desired valve contour.

[0054] As illustrated in FIG. 3D, accessory **11** (illustrated in FIG. 3A) can be positioned to align with native or prosthetic valve commissures C. As illustrated in FIG. 3E, accessory **12** (illustrated in FIG. 3B) can be positioned to straddle between each commissure C of the native or bioprosthetic aortic valve to aid in alignment with the THV commissure. As illustrated in FIG. 3F, accessory **13** (illustrated in FIG. 3C) can be positioned above the sinuses of the native or prosthetic valve in alignment with the valve leaflets L.

[0055] The accessory components can include radiopaque parts to aid in accurate visualization under fluoroscopy, and also include echogenic parts to aid in visualization under echocardiography. However, the accessory components will not have parts that would visually or mechanically interfere with visualization and accuracy of the THV deployment under fluoroscopy or echocardiography.

[0056] During the surgical procedure, the projections of the accessory **6** will be either in a first “aligned” configuration, e.g., aligned with the commissural posts **20** (illustrated with dotted lines) of the THV (illustrated in FIG. 4A with balloon expanding transcatheter heart valve **4** and FIG. 4B with self-expanding or mechanically-expanding transcatheter heart valve **40**), or alternatively, in a second “offset” configuration, e.g., offset by, e.g., 60 degrees (illustrated in FIG. 4C with balloon expanding transcatheter heart valve **4** and FIG. 4D with self-expanding or mechanically-expanding transcatheter heart valve **40**), at the base of sinus of transcatheter heart valve between two commissural posts **20** (illustrated with dotted lines), prior to mounting and crimping onto the delivery catheter such that during valve delivery and deployment the alignment will be maintained.

[0057] In some embodiments, the accessory 6 includes both a distal portion including distal projections 32 and a proximal portion 22 including proximal projections 31, such that after the THV 4 is positioned or deployed, the portion 22 of accessory 6 located proximal to the THV can be used to confirm orientation (FIG. 5A-5B). The base of the sinus of the transcatheter heart valve 21 is illustrated in FIG. 5B.

[0058] In some embodiments, e.g., system 100 (FIG. 2A), the valve delivery catheter 1 and the accessory 6, which can be independently manipulated, further include a locking and unlocking mechanism such that both parts can be locked together to maintain alignment between the accessory components and the THV commissures 20 in both “aligned” configuration (FIGS. 4A-4B) and “offset” configuration (FIGS. 4C-4D). In some embodiments, the locking mechanism is located within the handle/housing 26 (not shown).

[0059] In some embodiments, e.g., system 100 (FIG. 2B), because the valve delivery catheter 10 and the accessory 60 are a single unit, the THV commissures and the accessory components would be aligned at all times.

[0060] Alignment accessory control is provided. The delivery catheter 1 can include an independent mechanism to rotate the THV 4 and accessory 6 in unison to maintain the alignment between the components on the accessory and the THV commissures 20 to optimize the alignment between THV commissures 20 to the native or bioprosthetic aortic valve commissures, prior to valve implantation. This mechanism can include a turning wheel or knob 25 on the delivery system handle 26, such that one-to-one rotational alignment between the turning wheel 25 and the accessory 6 (not shown) is possible to allow accurate orientation of the THV relative to the native or bioprosthetic valve commissures or sinuses (FIG. 6A). FIG. 6B illustrates another embodiment of the knob 27 on system handle 26. Dotted arrows on FIGS. 6A and 6B illustrate rotation movement of knobs 25, 27, respectively. FIG. 6C illustrates another embodiment including a translational slide 28 operative with a helical screw or other similar configuration on system handle 26 to provide rotational alignment of the THV relative to the native or bioprosthetic valve commissures or sinuses. Solid arrows on FIG. 6C illustrate translation movement of slide 28.

[0061] The manual rotational alignment between the THV 4 and the native or bioprosthetic aortic valve commissures can occur prior to THV positioning across the native aortic annulus or bioprosthetic aortic valve, or after the THV 4 is fully deployed if the THV can be repositioned or recaptured.

[0062] FIG. 7A illustrates the balloon-expandable transcatheter heart valve 4 crimped prior to deployment. The accessory 6 is positioned at the aortic root 29 (including sinuses 29A, 29B, 29C) above the aortic valve annulus 30, such the projections 32 of accessory 6 are aligned with the native aortic valve commissures. The dashed line R illustrates rotational alignment of the transcatheter heart valve 4 with the commissures. Proximal portion 22 of the accessory 6 includes corresponding outwardly extending projections 31. Arrow D illustrates the direction of distal advancement of the transcatheter heart valve 4 and the accessory 6 across the annulus 30, resulting in the position of the transcatheter heart valve 4 and accessory 6 illustrated in FIG. 7B.

[0063] The case where the THV 4 would need to be partly or fully recaptured before rotational alignment can be performed, e.g., to avoid interaction with the native or bioprosthetic aortic valve, is illustrated in FIGS. 8A-8B. As illustrated in FIG. 8A, arrow R represents distal movement of the

valve delivery catheter 1 recapturing a self-expanding/mechanically-expanding transcatheter heart valve 40 which will recollapse the proximal components 22 of the accessory 6 within the catheter 1, resulting in the fluoroscopic view illustrated in FIG. 8B.

[0064] Additionally or alternatively, the alignment accessory control 2 can adjust the pitch and/or yaw of the THV 4/40 and/or accessory 6 to orient the components to conform to the native commissures. In some embodiments, the THV 4/40 and/or accessory 6 can be rotated up to 360 degrees; the pitch and yaw (measured relative to a longitudinal central axis of the THV) can be adjusted by up to 90 degrees.

[0065] In situations where the accessory components may straddle between each aortic valve commissure or to the base of the aortic sinus after THV deployment, the relative rotational misalignment between the accessory components and THV commissures can be visualized and identified by rotational fluoroscopy. In this case, the THV can be recaptured and repositioned for improved alignment with the native or bioprosthetic valve commissures, as visualized by the accessory components.

[0066] In balloon-expandable THV 4, the projections 32 of the accessory 6 may be loaded through the top row of open cells of the THV frame, such that the projections 32 will be positioned equidistant (60 degrees) from the three commissural posts. The projections 32 will be extended to position at the base of the three aortic sinuses 29A, 29B, 29C during THV positioning and deployment. FIG. 9 showing it can be mounted across the open cells of a balloon expandable transcatheter heart valve such that each component will be oriented and positioned above the base of the sinus prior to valve deployment.

[0067] After THV is deployed, these components of the accessory can be withdrawn and retrieved via the THV delivery system through an independent mechanism.

[0068] After the THV is deployed, the positions of the accessory components relative to the THV commissures identified on fluoroscopy determine the final THV orientation relative to the native or bioprosthetic aortic valve commissures. FIG. 10A illustrates the orientation of the accessory 6 after deployment of balloon-expandable transcatheter heart valve 4. FIG. 10B illustrates the orientation of the accessory 6 after deployment of self-expanding transcatheter heart valve 40.

[0069] The accessory components in system 100 may be manipulated and retracted after the THV is deployed. In system 200, after the valve delivery catheter is withdrawn from the THV, the accessory components can be resheathed over by the delivery catheter capsule to avoid interference with native issue to allow safe removal of the valve delivery system.

[0070] A cerebral embolic protection system may be mounted to the accessory to reduce stroke risk. In this version, the accessory components will span the diameter of the ascending aorta such that the cerebral embolic protection system can be fully deployed. In this version, only the accessory containing the cerebral embolic protection system will operate independently from the valve delivery catheter (similar to the interaction of catheter 1 and accessory 6 of system 100 described herein).

Mitral

[0071] Exemplary embodiments for delivery and implantation of a prosthetic mitral heart valve in a patient are

described herein. The delivery system can be either an antegrade (transseptal, transatrial) or retrograde (transapical) approach to the mitral valve (FIG. 1). The design principles of the delivery catheter and accessory are the substantially identical to the systems **100** and **200** described herein above; however, the delivery system lengths will vary based on the approach.

[0072] According to a first mitral embodiment (substantially identical to system **100**), the accessory **6**, located distal (+/-proximal) to the THV, includes at least three symmetric projections **32** that include radiopaque structures and a shaft to independently advance, rotate and retract within the delivery system. An advantage of this design is that if the THV needs to be recaptured and repositioned after complete deployment, and if recapturing and repositioning the device may lead to misalignment between the THV commissures and the accessory components, the accessory can be manually rotated to re-align with the THV commissures to confirm orientation relative to native or bioprosthetic valve commissures.

[0073] According to a second mitral embodiment (substantially identical to system **200**), the accessory **60**, located distal (+/-proximal) to the THV, can be an integral part of the valve delivery catheter **10**, whereby proximal unsheathing of the THV during deployment will expose the accessory **60** distal to the THV and hence at least the three visible projections **32**. This concept has a benefit of having a simpler delivery catheter with only one movable part (composite valve delivery catheter and accessory) instead of two separate independently movable parts.

[0074] As with the aortic accessory, the accessory components for the mitral application can take a variety of shapes, including soft and flexible filamentous projections that are atraumatic to the native tissue. The accessory components may be positioned to align with the commissures of the native mitral valve, center of posterior annulus, or bioprosthetic valve commissures, in addition to alignment with the THV commissures. The accessory components can include radiopaque parts to aid in accurate visualization under fluoroscopy, and also can include echogenic parts to aid in visualization under echocardiography. However, the accessory components will not have parts that would visually or mechanically interfere with visualization and accuracy of the THV deployment under fluoroscopy or echocardiography.

[0075] The components on the accessory will be aligned with the commissural posts of the THV prior to mounting and crimping onto the delivery catheter such that during valve delivery and deployment the alignment will be maintained. In the first mitral embodiment, the valve delivery catheter and the accessory, which can be independently manipulated, include a locking and unlocking mechanism such that both parts can be locked together to maintain alignment between the accessory components and the THV commissures. In the second mitral embodiment, because the valve delivery catheter and the accessory for a single unit, the THV commissures and the accessory components would be aligned at all times.

[0076] FIG. **11** illustrates the positioning of the system **100** with respect to the medial commissure **33**, the lateral commissure **34**, the anterior annulus **35**, and the posterior annulus **36** of the mitral valve. Accessory **6** includes projections **32** located distal to the transcatheter heart valve **4**, to be oriented to the medial and lateral commissures, and the

distal portion of the accessory **22** includes projections **31** located proximal to the transcatheter heart valve **4**, to be oriented to the medial and lateral commissures. The projections **31** and **32** are oriented 120 degrees apart from each other to aid in alignment of transcatheter heart valves with prosthetic heart valves. In some embodiments, one projection of the accessory **6** will always face the middle of the posterior mitral valve annulus **36**.

[0077] FIG. **12** illustrates the orientation of the transcatheter heart valve **4** in its crimped form, aided by the projections **31**, **32** to align with the commissures **20** of the prosthetic heart valve **37**.

[0078] The delivery catheter includes an independent mechanism to rotate the THV and accessory in unison to maintain the alignment between the components on the accessory and the THV commissures to optimize the alignment between THV commissures to the native mitral valve commissures and the center of posterior mitral annulus, or bioprosthetic mitral valve commissural posts, prior to THV implantation. In some embodiments, this mechanism is a turning wheel or knob on the delivery system handle, such that one-to-one rotational alignment between the turning wheel and the accessory is possible to allow accurate orientation of the THV relative to the native commissures and center of the posterior annulus or bioprosthetic mitral valve commissures. (See, e.g., FIGS. **6A-6C**).

[0079] The manual rotational alignment between the THV and the native or bioprosthetic mitral valve commissures can occur prior to or during THV positioning across the native mitral annulus or bioprosthetic mitral valve, or after the THV is fully deployed if the THV can be repositioned or recaptured (FIGS. **13A**, **14A**). In the latter case, the THV would need to be partly or fully recaptured before rotational alignment can be performed to avoid THV interacting with the native or bioprosthetic mitral valve.

[0080] In situations where the accessory components face the native mitral commissures and center of posterior annulus, or the bioprosthetic mitral commissures, after THV deployment, the relative rotational misalignment between the accessory components and THV commissures can be visualized and identified. In this case, the THV can be recaptured and repositioned for improved alignment relative to the commissures, as visualized by the accessory components.

[0081] After the THV is deployed, the positions of the accessory components relative to the THV commissures identified on fluoroscopy determine the final THV orientation relative to the native or bioprosthetic mitral valve commissures (FIG. **13B**, **14B**).

[0082] The accessory components in system **100** may be manipulated and retracted after the THV is deployed. In system **200**, after the valve delivery catheter is withdrawn from the THV, the accessory components can be resheathed over by the delivery catheter capsule to avoid interference with native issue to allow safe removal of the valve delivery system.

Tricuspid

[0083] Exemplary embodiments for delivery and implantation of a prosthetic tricuspid heart valve in a patient are described herein. The delivery system will be an antegrade (transfemoral, transjugular, transaxillary) approach to the tricuspid valve (FIG. **1**). The design principles of the delivery catheter and accessory are the same as for the mitral

valve but the accessory will consist of components based on the anatomy of the native or bioprosthetic tricuspid valve.

[0084] Having described and illustrated the principles of our invention with reference to the described embodiments, it will be recognized that the described embodiments can be modified in arrangement and detail without departing from such principles. It should be understood that the systems, processes, or methods described herein are not related or limited to any particular type of environment, unless indicated otherwise.

[0085] In view of the many possible embodiments to which the principles of our invention can be applied, we claim as our invention all such embodiments as can come within the scope and spirit of the following claims and equivalents thereto.

What is claimed is:

1. A delivery system for a transcatheter heart valve (THV) to a subject, the delivery system comprising:

- a delivery catheter sized for housing the THV therein;
- an elongated member for receiving the THV thereon and having an accessory extending from the distal portion thereof, the accessory comprising a plurality of radially outwardly extending projections disposed distally from the THV during delivery of the THV for alignment of the THV with respect to a native or bioprosthetic valve commissure or a valve leaflet at a desired angle during delivery of the THV, the elongated member and accessory independently rotatable with respect to the delivery catheter, and
- a rotational member connected to the elongated member to rotate the accessory and THV together to align with a native or bioprosthetic valve commissure or a valve leaflet at a desired angle.

2. The delivery system of claim 1, further comprising projections disposed at a proximal portion of the THV during delivery of the THV.

3. The delivery system of claim 2, wherein the projections extend radially outwardly from the elongated member.

4. The delivery system of claim 1, wherein the projections are atraumatic filamentous projections.

5. The delivery system of claim 1, wherein the projections are loop-shaped projections.

6. The delivery system of claim 1, wherein the projections comprise radiopaque components.

7. The delivery system of claim 1, wherein the projections are capable of being extended or retracted from the elongated member

8. The delivery system of claim 1, wherein each projection is capable of being moved independently.

9. The delivery system of claim 1, wherein one or more of the projections is curled to conform to a contour of the native or bioprosthetic valve.

10. The delivery system of claim 1, wherein the rotational member comprises a control member positioned on a proximal handle portion.

11. The delivery system of claim 10, wherein the control member is a rotational wheel.

12. The delivery system of claim 10, wherein the control member is a thumb slide.

13. The delivery system of claim 1, wherein the delivery catheter, the elongated member and the THV are adapted for deployment to the aortic valve of the subject.

14. The delivery system of claim 1, wherein the THV is adapted for placement at the mitral valve of the subject.

15. The delivery system of claim 1, wherein the THV is adapted for placement at the tricuspid valve of the subject.

16. The delivery system of claim 1, wherein the radially outwardly extending projections have elastic or shape memory characteristics.

17. The delivery system of claim 16, further comprising a nose cone positioned distal of the accessory.

18. The delivery system of claim 17, wherein the projections are capable of being compressed within the delivery catheter during delivery.

19. The delivery system of claim 18, wherein the nose cone is capable of being advanced distally from the projections to allow the projections to extend from the compressed configuration to the radially outward configuration.

20. A method for delivery of a transcatheter heart valve (THV) to a subject comprising:

- providing an elongated member for receiving the THV thereon and having an accessory extending from the distal portion thereof, the accessory comprising a plurality of radially outwardly extending projections disposed at a distal portion of the THV, the elongated member and accessory housed within and independently rotatable with respect to a delivery catheter;
- deploying the elongated member and THV from the delivery catheter at the native valve location;
- rotating the accessory to align the THV with respect to a native or bioprosthetic valve commissure or a valve leaflet at a desired angle; and
- expanding the THV in the valve location.

21. The method of claim 20, further comprising a nose cone disposed at a distal end of the elongated member.

22. The method of claim 21, further comprising, prior to deploying the elongated member, compressing the projections within the delivery catheter into a compressed configuration.

23. The method of claim 22, further comprising, after compressing the projections, advancing the projections to expand to a radially outward configuration.

24. The method of claim 20, wherein the valve location is the aortic valve.

25. The method of claim 20, wherein the valve location is the mitral valve.

26. The method of claim 20, wherein the valve location is the tricuspid valve.

27. The method of claim 20, wherein rotating the accessory comprises rotating the accessory to align the radially outwardly extending projections with the native or bioprosthetic valve commissure.

28. The method of claim 20, wherein rotating the accessory comprises rotating the accessory such that the radially outwardly extending projections straddle the native or bioprosthetic valve commissure.

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